REMARKS

I. Status of the Claims

Claims 1-6, 8-24, and 26-41 are pending in this application. Claims 7 and 25 have been canceled. Claims 30-38 have been withdrawn from consideration. Claims 39-41 are new. Claims 1, 5, 8-17, 19, and 26-29 have been amended as discussed in further detail below.

Applicants acknowledge and appreciate the Examiner's withdrawal of the rejection of claims 1-16 under 35 U.S.C. § 102(b) and § 103 in light of PCT Publication No. WO 96/20703 ("Wu").

II. Rejections under 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 1-29 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (*Office Action* at p. 2.) Applicants respectfully traverse this rejection.

A. The Examiner alleges that "the specification provides no evidence that Gibberellin alone is effective in lowering blood glucose levels." (*Id.*) According to the Examiner, Applicants have not provided any evidence of the effectiveness of the claimed method. (*Id.*)

Applicants respectfully disagree. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (M.P.E.P. § 2164.01.)

Applicants respectfully submit that the specification does enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation.

Specifically, one of ordinary skill would readily appreciate that the disclosure of Example 5 enables the use of Gibberellins alone to treat Type II diabetes mellitus and its complications and associated conditions, and the use of Gibberellins and a substance, such as insulin, for treating Type I diabetes mellitus and its complications and associated conditions. Such enablement is demonstrated in the attached declaration of Dr. Peter Jenkins (the "Declaration"), an inventor of the present application, regarding Example 5 for the treatment of Type I and Type II diabetes.

A skilled artisan would have known that Type I diabetic humans and animals may produce trace amounts of endogenous insulin, although this typically ceases altogether after a few years. (*Declaration* at p. 3.) Treatment of Type I diabetes usually requires administration of insulin. (*Id.* at p. 8.) A skilled artisan would also have known that Type II diabetics differ in that they typically have some endogenous insulin but produce an amount of insulin that is insufficient to adequately control their blood glucose level, either due to decreased insulin production and/or decreased sensitivity to insulin. (*Id.* at p. 3-4.)

Example 5 illustrates treatment of Type I and Type II diabetic rats. Specifically, Example 5 describes experiments with male Wistar rats that were induced with diabetes by administration of 60 mg/kg of streptozocin. (*See Specification* at p. 22.) The resulting blood glucose level of ≥16 mM indicated that the rats were unequivocally diabetic. (*Declaration* at p. 4.) Streptozocin acts upon pancreatic β-cells and prevents endogenous production of insulin. (*Id.*) The skilled artisan would have appreciated that the amount of streptozocin adminstered would have induced Type I diabetes through

the death of pancreatic β-cells. (*Id.* at p. 5.) Thus, Group Nos. 1-5 each had Type I diabetes at the outset of their treatment as described in the specification at pp. 22-23.

One of ordinary skill would appreciate that a blood glucose level of 4-6 mM is considered to be a normal level. (*Id.*) In Example 5, administration of 4 units/rat of insulin to Group No. 1 rats brought their blood glucose level to ranges that overlapped with the 4-6 mM range, such that one of ordinary skill would have considered these rats to have achieved a normal blood glucose level. (*Id.* at p. 6.) In contrast, Group No. 2 rats, which were treated with only 2 units/rat of insulin, had blood glucose levels overlapping the ≥16 mM range, a range considered to be diabetic. (*Id.* at pp. 6-7.) Thus, 4 units/rat of insulin was sufficient to normalize the blood glucose levels of rats having Type I diabetes, but 2 units/rat of insulin was insufficient to bring their blood glucose level to a normal range.

Treatment of Group Nos. 3-5 rats with 2 units/insulin and 5 mg/kg of Gibberellin A_3 resulted in blood glucose levels in the range of 4-6 mM, the range considered to be normal. (*Id.* at p. 7.) Here, the Group Nos. 3-5 rats had Type I diabetes at the beginning of the experiment, and 2 units/rat insulin alone had been shown to be insufficient to attain a normal blood glucose level in the Group No. 2 rats. However, treatment with both Gibberellin A_3 and an insufficient amount of insulin (2 units/rat) successfully brought the blood glucose level to a normal range in the Group Nos. 3-5 rats. Thus, the treatment of the Group Nos. 3-5 rats with Gibberellin A_3, in combination with a substance such as insulin, fully enables the effective treatment of Type I diabetes (*see Id.* at p. 8-9), and claims relation to such treatment.

Furthermore, the treatment of the Group Nos. 3-5 rats demonstrates the effective treatment of Type II diabetes. Administration of 2 units/rat insulin to the Group Nos. 3-5 rats resulted in their having an insufficient amount of insulin to normalize their blood glucose level as in the Type II diabetic model, similar to the Group No. 2 rats. (*Id.* at p. 9.) However, in contrast to Group No. 2 rats, whose blood glucose levels were in the diabetic range, Group Nos. 3-5 were additionally treated with Gibberellin A_3. (*Id.*) Because the administration of 2 units/rat insulin is shown to replicate the situation of Type II diabetes, where small amounts of insulin may exist but in an insufficient amount to control blood glucose levels, the Group Nos. 3-5 rats were effectively treated by the administration of Gibberellin A_3 alone. (*Id.*) Thus, Example 5 fully enables the treatment of Type II diabetes through administration of Gibberellin A_3 alone. (*Id.*)

Applicants have amended independent claims 1 and 8 to recite a method of treatment for Type II diabetes and its complications and associated conditions. Independent claims 11 and 12 have been amended to recite a method of treatment for Type I and Type II diabetes and its complications and associated conditions. The term "related conditions" has been amended to "complications and associated conditions" in claims 8, 11 and 12. Claims 13-15 have been amended to depend from claim 11. New claim 39 depends from claim 11 and requires the complications and associated conditions of diabetes to be one or more of: obesity, micro and macro vascular diseases, nephropathy, neuropathy, eye diseases, and diabetic ulcerations. Support for all of the above amendments and new claim 39 can be found in the specification, for example, at p. 1, lines 30-34. Claims 9 and 10 have been amended to depend from

claim 11. Support for these amendments can be found in the specification, for example, at p. 5, line 33, to p. 6, line 2.

In addition, claim 8 has been amended to require the combination with other compatible therapeutic agents as recited therein. Support for this amendment can be found in the specification, for example, at p. 17, lines 18-24. Claim 12 has been amended to include the combination with substances selected from the group consisting of insulin, its fragment derivatives, IGF's, growth factors and other pharmaceutically compatible anti-diabetic agents. Support for this amendment can be found in the specification, for example, at p. 12, lines 1-6. Claim 16 has been amended to remove a comma, which corrects an obvious typographical error. Thus, Applicants respectfully submit that no new matter has been added by these amendments.

Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112.

B. The Examiner also alleges lack of enablement in the use of the term "glycosidic [*sic*, glycosylic]." (*Office Action* at p. 2.) The Examiner contends that the term encompasses mono-, di-, and polysaccharides without providing guidance in how to select from among these choices. (*Id.*) According to the Examiner, the term "glycosidic" does not satisfy the factors set forth in *In re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)) for analyzing whether undue experimentation would be required to make and use the invention. (*Id.* at pp. 2-4.) Applicants respectfully traverse this rejection.

In determining enablement, it is noted that the specification "need not teach, and preferably omits, what is well known in the art." (M.P.E.P. § 2164.01.) Applicants

respectfully submit that the term "glycosidic" or its cogeners (e.g., glycoside) are terms that are well known to the skilled artisan. For example, U.S. Patent No. 5,580,857 ("Oden '857") teaches that preferred Gibberellins for use in its invention comprise those of Group F, Gibberellin conjugates such as Gibberellin ethers and esters. (*Oden '857* at col. 4, lines 63-64.) Oden '857 describes preferred exemplary ethers and esters, which include glycosylic ethers and esters. (*Id.* at col. 4, line 62, to col. 5, line 30.)

The teachings of Oden '857 serve either to educate those skilled in the art as to the novel Gibberellin conjugates disclosed therein, or to recite a genus of Gibberellin conjugates comprising species already familiar to the skilled artisan. The fact that the claimed invention in Oden '857 is not directed to a compound or composition comprising the disclosed Gibberellin conjugates, but to a method for decreasing prostate mass comprising administering an effective amount of a Gibberellin (*see id.* at col. 14, line 19, to col. 16, line 47), supports the conclusion that the Gibberellin conjugates themselves were already known in the art. However, even if, for the sake of argument, the Gibberellin conjugates were previously unknown prior to Oden '857 in the art, publication of the Oden '857 patent would have served to familiarize those of ordinary skill in the art with the disclosed genus. Applicants respectfully submit that the Gibberellin conjugates, including glycosylic esters and ethers, described in Oden '857 were well known in the art as of Oden '857's filing date of January 24, 1994, which is prior to the present application's filing date by over 10 years.

In addition, Davis et al., *Journal of the American Podiatric Medical Association* (1989) 79:1, 24-26 ("Davis") describes "gibberellin" in the following manner.

> "The authors determine if *gibberellin, a glycoside* and growth hormone found in plants, could account for some of the anti-inflammatory activity..."

(*Davis* at p. 24) (emphasis added). Davis' characterization of "gibberellin" as a "glycoside" indicates that the term "glycoside" was sufficiently well known as of its publication date, January, 1989, such that one of ordinary skill would not require further explanation. Thus, Davis provides further evidence that the tem "glycoside" in the present context is a term well known in the art and thus does not require a teaching beyond that given in the specification. (*see* M.P.E.P. 2164.01.)

Given the knowledge in the field, the skilled artisan would be able to synthesize the claimed glycosyl ethers and esters in a routine manner. Moreover, the specification at Examples 5-6 provides clear guidance on how to evaluate compounds of formula 1 for use in the claimed method, i.e., monitoring serum glucose levels. (*See Specification* at pp. 22-23.) Such guidance, coupled with the knowledge in the art, have been shown to be sufficient evidence of enablement. *In re Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988). Thus, the specification enables one of ordinary skill in the art to make and use the claimed invention through routine experimentation.

Applicants respectfully request withdrawal of this rejection under 35 U.S.C § 112.

C. The Examiner also alleges lack of enablement in the use of the terms "allyl, aryl, arylalkyl, amidine, and unsaturated or saturated ring." (*Office Action* at p. 3.) For example, the Examiner alleges that "'allyl' encompasses an allyl having 3 carbon atoms and an allyl having 100 atoms and everything in between." (*Id.*) Because these terms have allegedly not been limited to a range of carbon atoms, the Examiner

contends that "it would take an undue amount of experimentation" to identify compounds with desired activity. (*Id.*)

Applicants disagree with the Examiner's characterization of the terms "allyl" and "amidine." An allyl group is well known in the art to be a trivial, or common, name for 2-propenyl, i.e., the structure $-CH_2CH=CH_2$. This understanding is supported by its usage in introductory organic chemistry texts. (*See,* e.g., Roberts et al., *Basic Principles of Organic Chemistry,* New York: W. A. Benjamin Co., 1964, 148 ("Roberts"), and Loudon, M. *Organic Chemistry*, 3rd Ed. Redwood City, CA: Benjamin/Cummings Publishing Co., Inc., 1995, 131 ("Loudon")). The term amidine is well known in the art to refer to the structure $-C(=NH)NH_2$. (*See,* e.g., March, J., *Advanced Organic Chemistry*, 4th Ed. New York: J. Wiley and Sons, 1992, 423 ("March")). Therefore, an undue amount of experimentation would not be required of the skilled artisan to determine the chemical structures encompassed by the terms allyl and amidine.

In considering whether experimentation is undue, "time and difficulty of experiments are not determinative if they are merely routine." (M.P.E.P. § 2164.06.) Here, the terms "aryl," "arylalkyl" and "unsaturated or saturated ring" also have definitions that are well known to one of ordinary skill in the art. For example, Loudon indicates that the term "aryl" generally refers to "a benzene ring or substituted benzene ring cited as a substituent." (*Loudon* at p. 739.) Coupled with the disclosure of alkyl in the specification, Applicants respectfully submit that one of ordinary skill in the art would readily understand the meaning of the term arylalkyl to be an aryl group bonded to an alkyl group. The skilled artisan would also appreciate that the term "unsaturated or

saturated ring" refers to a genus of cyclic compounds which can be readily distinguished from compounds not fitting that description.

Moreover, the specification at Examples 5-6 provides clear guidance on how to evaluate compounds of formula 1 for use in the claimed method, i.e., monitoring serum glucose levels. (*See Specification* at pp. 22-23.) As the specification provides clear procedures on how to evaluate the disclosed compounds for use in the claimed methods, one of ordinary skill in the art would not require an undue amount of experimentation to identify compounds with the desired activity.

Applicants respectfully request withdrawal of this rejection under 35 U.S.C § 112.

III. Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-29 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in the use of the term "derivatives." (*Office Action* at p. 5.)

While Applicants disagree with the position of the Examiner, to advance prosecution, Applicants have amended method claims 1, 8, 11, 12 and 29 to recite administering a compound selected from formula (1) and its pharmaceutically acceptable lactones, esters, active esters, salts and organic bases. Claim 5 has been amended to require pharmaceutically acceptable salts. Similarly, anti-diabetic agent claims 17 and 19 have been amended to recite pharmaceutically acceptable lactones, esters, active esters, salts and organic bases. Support for these amendments can be found in the specification, for example, at p. 1, lines 13-18, and p. 8, line 33, to p. 9, line 4. Claims 26-28 have been amended to depend from claim 17. Claims 26 and 27 have been amended to recite a pharmaceutically acceptable salt, while claim 28 has been

amended to recite a pharmaceutically acceptable ester. Support for these amendments can be found in the specification, for example, at p. 11, lines 1-29.

New claim 40 depends from claim 11 and requires the pharmaceutically acceptable salts to be selected from alkali metal salts, alkaline earth metal salts, metal, and salts of ammonium or organic bases. New claim 41 depends from claim 40 and recites a genus of organic bases. Support for claims 40 and 41 can be found in the specification, for example, at p. 8, line 33, to p. 9, line 4. Thus, Applicants respectfully submit that no new matter has been added by these amendments.

Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112.

IV. Rejections under 35 U.S.C. §§ 102 and 103

The Examiner has maintained the rejection of claims 17-29 under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Oden '857, Wu, WO 94/24260 ("Oden WO 94/24260") or EP 0 024 951 B1 ("Graebbe"). (*Id.* at p. 5.)

The Examiner has not given patentable weight to the term "anti-diabetic" because the recitation occurs in the preamble and allegedly only recites the intended use of the claimed structure. (*Id.* at p. 6.) According to the Examiner, "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art" for the claimed invention to be patentably distinct. (*Id.*) The Examiner also alleges that the cited prior art does not require carriers such as glucose or sucrose. (*Id.*) Applicants respectfully traverse these rejections.

Further, claims 1-29 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Davis. (*Office Action* at p. 7.) According to the Examiner, Applicants argued "that Davis does disclose the treatment of diabetes." (*Id.*) (emphasis added). The Examiner contends that "it is clear from the disclosure by Davis that wounds and inflammation are complications and conditions associated with diabetes." (*Id.*) Furthermore, the Examiner alleges that Davis "clearly teaches the use of gibberellin for the treatment of conditions associated with diabetes. (*Id.*) Applicants respectfully traverse this rejection.

Background

"A claim is anticipated only if *each and every element as set forth in the claim* is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)) (emphasis added). Moreover, a *prima facie* case of obviousness is established only if the prior art reference teaches or suggests every element of the claimed invention. (M.P.E.P. § 2143.01.) Neither of these standards have not been met by the cited references.

Claims 17-29 (17 and 19 are independent) are directed to an anti-diabetic agent. The term "anti-diabetic agent" does not simply recite an intended use but rather indicates the compounds that are suitable for administration to a diabetic patient. One of ordinary skill in the art would readily appreciate that compositions comprising sugar would be not be consonant with the meaning of the term anti-diabetic agent. For example, the Children's Medical Center at the University of Virginia warns against the use of pharmaceutical excipients that contain sugar in preparations for administration to

children with diabetes. (Children's Medical Center at the University of Virginia, *Pediatric Pharmacotherapy*, 2:1-4 (1996).) They advise that "use of products containing large amounts of sugar should be avoided in children with diabetes, whenever possible" and recommend regular blood glucose monitoring if they must be used. (*Id.*) Similarly, Express Scripts, Inc., a pharmacy benefit manager company, warns readers on its web site, www.drugdigest.org, to be aware of antacids that contain sugar if they are diabetic, and indicates sugar-free antacids are available. (Express Scripts, Inc., http://www.drugdigest.org/DD/PrintablePages/Comparisons/1,20038,8-21,00.html, printed on 03/08/2005.) Thus, the need for diabetics to avoid consuming sugar in pharmaceutical compositions is well known in the art.

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." (M.P.E.P. § 2111.02.) Furthermore, "any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." (*Id.*)

In requiring an anti-diabetic agent, the present claims are a patentable selection among a broad range of known pharmaceutical compositions, many of which are not suitable as anti-diabetic agents. For example, a pharmaceutical composition comprising a pharmaceutically acceptable carrier such as glucose or sucrose would not be a suitable anti-diabetic agent and thus, would not be within the scope of claims 17-29. The meaning of the term "anti-diabetic" functions to exclude compositions that contain sugar. The anti-diabetic agent recited in the preamble thus adds a structural limitation to the claimed composition, as "anti-diabetic" unequivocally connotes the

absence of sugar. Thus, the term "anti-diabetic agent" must be treated as a claim limitation in accord with M.P.E.P. § 2111.02.

Furthermore, Applicants have amended independent claims 17 and 19 to require "[a]n anti-diabetic agent consisting essentially of a compound of formula (1)...." The "consisting essentially of" transitional phrase limits the scope of the claims to the specified components and "those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. (M.P.E.P. § 2111.03) (emphasis in original). Applicants have the burden of showing that the introduction of additional steps or components would materially change the characteristics of Applicants' invention. (*Id.*)

One of the novel characteristics of the claimed anti-diabetic agent is its compatibility with the need for diabetics to avoid unnecessary sugar consumption, as discussed above. Therefore, addition of sugar would materially affect the basic and novel characteristics of the claimed composition by decreasing, if not altogether eliminating, its suitability for administration to diabetics. The well known need for diabetics to avoid sugar consumption meets the burden of proof necessary to show that addition of sugar would materially change the basic and novel characteristics of the claimed anti-diabetic agent. Thus, the transitional phrase in claims 17-29 reinforces the limitation imposed by the meaning of the term "anti-diabetic" itself, namely that the anti-diabetic agent is a composition that requires the absence of sugar.

Wu

Wu describes the use of gibberellin compounds and corresponding pharmaceutical compositions for treating wounds, ulcers, and lesions, and for cultivation

of skin cell lines. (*Wu* at p. 3.) However, Wu does not disclose, teach, or suggest an anti-diabetic agent.

The pharmaceutical compositions of Wu's invention may contain sugar, as evidenced by its claim 10. (*Wu* at p. 18.) Specifically, claim 10 requires a carrier selected from a genus that includes sucrose and lactose. (*Id.*) While its claimed pharmaceutical compositions do not require sugar, they do not exclude it: the open-ended transitional phrase "including" in its independent composition claim 9 allows for sugar to be a component of the composition. (*See Id.* at p. 17-18.) Wu provides no disclosure of an anti-diabetic composition comprising gibberellin that requires the absence of sugar. Furthermore, Wu provides no teaching or suggestion of a composition that excludes sugar. Therefore, Wu neither anticipates nor renders obvious the present claims.

Oden

Sinilarly, Oden '857 and Oden WO 94/24260 do not teach anti-diabetic uses of gibberellin compounds. Namely, Oden '857 discloses the use of gibberellin compounds for the treatment of prostatitis and psoriasis. (*Oden '857* at col. 2, lines 31-34.) Oden WO 94/24260 discloses a composition "containing one or more gibberellins with activity against androgenic alopecia." (*Oden WO 94/24260* at p. 5.)

As discussed above, claims 17-29 are directed to anti-diabetic agents and thus, only encompass those compositions suitable as anti-diabetic agents. Oden '857 and Oden WO 94/24260 do not disclose, teach, or suggest an anti-diabetic agent requiring the absence of sugar. Thus, claims 17-29 are patentable over Oden '857 and Oden WO 94/24260.

Graebbe

Graebbe is directed to "a new process for the production of gibberellins by fermentation." (*Graebbe* at col. 1, lines 1-4.) Graebbe, however does not disclose, teach, or suggest a pharmaceutically acceptable carrier or excipient, much less the claimed anti-diabetic agent requiring the absence of sugar. Thus, claims 17-29 are patentable over Graebbe.

Davis

The Examiner has mischaracterized Applicants' arguments regarding Davis presented in response to the Office Action dated January 26, 2005. Applicants did not state that Davis discloses the treatment of diabetes, as asserted by the Examiner. (*Office Action* at p. 7.) Rather, Applicants argued that "Davis does not teach or suggest a method of treating diabetes and its complications and associated conditions, as claimed." (*Response to Office Action* dated January 26, 2005, at p. 33) (emphasis added). Accordingly, Applicants respectfully request clarification of the record by the Examiner.

In contrast to the claimed invention, Davis teaches a method of treating inflammation using a composition containing gibberellin. (*Davis* at p. 24.) Davis used diabetic mice in its study "because of their poor healing and anti-inflammatory capabilities." (*Id.*) Davis created a site of inflammation on the mice by subcutaneous injection of a 2% gelatin solution. (*Id.* at p. 25.) After administration of a gibberellin solution, the mice were killed three hours later for analysis of inflammation activity. (*Id.* at p. 25.) Davis does not address or mention the treatment of diabetes.

The Examiner alleges that Davis inherently treats diabetes. However, to establish inherency, the allegedly inherently characteristic must necessarily flow from the teachings of the prior art reference. (M.P.E.P. § 2112.IV; *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999)). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (*In re Rijckaert* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original)).

Davis uses the condition of diabetes to create an animal model with poor healing and anti-inflammatory capabilities. Davis is silent on whether the observed wound and inflammatory conditions are intrinsic to the diabetic state, *i.e.*, that they are a complication or an associated condition of diabetes itself, or whether these conditions are created by the action of a mechanism other than diabetes. However, the evidence presented in Davis supports the latter conclusion. The mice used in the study did not suffer a wound as a result of diabetes. Instead, the wound was inflicted by Davis when he deliberately injected the mice with the 2% gelatin solution. The observed inflammation bleb following the injection resulted from the 2% gelatin. (*See Davis* at p. 25.) Thus, Davis' subsequent treatment of the mice with Gibberellin represents the treatment of wounds and inflammation created by Davis, not conditions resulting from diabetes.

Even if, for the sake of argument, Davis is interpreted to describe the treatment of wounds and inflammation associated with diabetes, the present claims are directed to a method for treating diabetes and its complications and associated conditions. Davis does not disclose, teach or suggest a treatment for diabetes, such as the normalization

of blood glucose levels. From the disclosure and teachings of Davis alone, the skilled artisan would readily appreciate that a method for treating inflammation has been provided, that a method for treating diabetes and its complications and associated conditions is not described and does not necessarily flow from the method described by Davis, as would be required for an inherent disclosure of the presently claimed method. (*See* M.P.E.P. § 2112.) Accordingly, Davis does not expressly or inherently describe the method as claimed.

Davis does not teach or suggest a method of treating diabetes and its complications and associated conditions, as claimed. Rather, Davis teaches compositions for anti-inflammatory purposes. Thus, Davis does not present a *prima facie* case of obviousness over the claimed method.

Finally, Davis does not disclose, teach, or suggest an anti-diabetic agent as recited in claims 17-29 for the same reasons discussed above for Wu.

Accordingly, Applicants respectfully request withdrawal of these rejections.

V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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